K121563 #1/3

3. 510(K) SUMMARY

1. **Applicant/Sponsor:** Corin USA
10500 University Center Drive
Suite 190
Tampa, Florida 33612
Establishment Registration No.:1056629

OCT 5 2012

2. **Contact Person:** Lucinda Gerber
Regulatory Affairs Associate
Corin USA
813-977-4469
lucinda.gerber@coringroup.com

3. **Date:** May 25, 2012

4. **Proprietary Name:** Corin Trifit TS Hip

5. **Common Name:** Hip Prosthesis

6. **Classification Name:** Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353)

Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21CFR 888.3390)

Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21CFR 888.3360)

7. **Legally Marketed Devices to which Substantial Equivalence is claimed:**

- Biomet Laterlized Taperloc® Microplasty™ Femoral Components (K062994)
- DePuy Titanium Tri-Lock Hip Stem (K010367)
- DePuy Tri-Lock Bone Preservation Stem (K073570)
- Corin Metafix Hip Stem with Hemi-Arthroplasty (120362)
- Corin Trinity Acetabular System (K093472)

8. **Device Description:**

The Corin TriFit TS Hip is a double tapered-wedge blade stem design manufactured from Ti6Al4V Titanium alloy (ASTM F-136-08) with a layer of commercially pure titanium (BS ISO 5832-2: 1999) and calcium phosphate(BONIT®)coating(ASTM F1609-08) applied. The TriFit TS Hip is available in a range of sizes in standard and

lateralized offsets with a 127° CCD angle. The device isintended to be used with Corin 12/14 modular taper heads.

The TriFit TS Hip is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients wherethere is evidence of sufficient sound bone to seat and support the components.

9. Intended Use / Indications:

The indications for the Corin TriFit TS Hip as a total hip arthroplasty, and when used in combination with a Corin hemi arthroplasty head, as a hip hemi-arthroplasty, include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur
- Developmental dysplasia of the hip (DDH) or congenital dysplasia of the hip (CDH)

The TriFit TS Hip is intended for cementless use only.

10. Summary of Technologies/Substantial Equivalence:

The TriFit TS Hipis similar to the Biomet Taperloc® Microplasty™ (K062994) and the DePuy Tri-Lock (K010367, K073570) hip stems in terms of materials, sizes, designs, performance, intended use and indications for use. It is identical to the Corin Metafix Hip Stem (K120362) in terms of intended use and indications and similar in materials. The coating of titanium plasma spray with a layer ofcalcium phosphate(BONIT®) is similar to the coating for the Corin Trinity Acetabular System.(K093472) in terms of materials and performance. Based on these similarities, the TriFit TS Hip is believed to be substantially equivalent to the predicate devices.

11. Non-Clinical Testing:

Non-clinical testing conducted to demonstrate substantial equivalence is consistent with "Guidance for Industry and FDA Staff Non-clinical Information for Femoral Stem Prosthesis" and includes: femoral hip stem fatigue (ISO 7206-4: 2010), femoral stem neck fatigue (ISO 7206-6: 1992 and ASTM F2068-03 Standard Specification for Femoral Prostheses andRange of Motion analysisconsistent with ISO 21535:2009. All 6 stems passed hip stem fatigue testing for 5 million cycles (mc) at 2.3 kN meeting the acceptance criteria. All 6 stems passed stem neck fatigue for 10 mc at 5.34 kN, meeting

the acceptance criteria. The minimum Range of Motion passed its simulation, meeting the acceptance criteria.

The underlying plasma sprayed CPTi coating thickness was tested for porosity,pore size, thickness, surface roughness, mechanical strength (static tensile, static shear, shear fatigue) and taper abrasion in line with the requirements of 'Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement'. The calcium phosphate coating (BONIT®) applied by electrochemical deposition to the CPTi coating was characterized per FDA's "510(k) Information needed for Hydroxyapatite Coated Orthopedic Implants." The dual nonporous coating (calcium phosphate coating overlying the CPTi coating) underwent additional testing in order to determine the thickness, porosity and pore diameter of the combined coating in accordance with ASTM F1854, as well as bending fatigue testing.

12. Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the additional components of the Corin TriFit TS Hip stem and the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 5 2012

Corin USA
% Ms. Lucinda Gerber
Regulatory Affairs Associate
10500 University Center Drive, Suite 190
Tampa, Florida 33612

Re: K121563
Trade/Device Name: TriFit TS Hip
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH, LZO, KWL, KWY
Dated: September 07, 2012
Received: September 10, 2012

Dear Ms. Gerber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin M. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K121563

Device Name: TriFit TS Hip

Indications for Use:

The indications for the Corin TriFit TS Hip as a total hip arthroplasty, and when used in combination with a Corin hemi arthroplasty head, as a hip hemi-arthroplasty, include:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
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The TriFit TS Hip is intended for cementless use only.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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